

CONSUMER MEDICINE INFORMATION

ORALAIR[®]

Pronounced (O-ral-air)

Contains the active ingredients of allergens from a mixture of 5 grass pollens

Table of contents

<i>What is in the leaflet</i>	<i>p. 1</i>
<i>What is Oralair used for</i>	<i>p. 1</i>
<i>Before you are given Oralair</i>	<i>p. 2</i>
<i>How Oralair is given</i>	<i>p. 3</i>
<i>While you are receiving Oralair</i>	<i>p. 5</i>
<i>Side effects</i>	<i>p. 7</i>
<i>After using Oralair</i>	<i>p. 7</i>
<i>Product description</i>	<i>p. 7</i>
<i>Presentation</i>	<i>p. 8</i>

What is in this leaflet

This leaflet answers some common questions about Oralair Initiation Treatment and Oralair Continuation Treatment sublingual tablets.

It does not contain all the available information.

It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Oralair against the expected benefits it will have for you.

If you have any concerns about taking this medicine, ask your doctor.

What is Oralair used for

Oralair contains an allergen extract. Treatment with Oralair is intended to increase the immunological tolerance towards certain grass pollens, thereby reducing the allergic symptoms.

Oralair is used for the treatment of certain grass pollen allergies that are characterised by rhinitis (sneezing, runny or itchy nose, nasal congestion) with or without conjunctivitis (itchy and watery eyes) in adults, adolescents and children above the age of 5.

Before treatment, the allergy is confirmed by a doctor with adequate training and experience in allergic diseases, who will perform the appropriate skin and/or blood tests.

The grass pollens that Oralair is used for are: *Dactylis glomerata* (cocksfoot); *Lolium perenne* (rye grass); *Anthoxanthum odoratum* (sweet vernal grass); *Phleum pratense* (timothy) and *Poa pratensis* (meadow grass).

How it works:

Treatment with Oralair is intended to increase the immunological tolerance towards grass pollens, thereby building immunity to the specific allergens in grass pollens, thus helping to reduce the allergic symptoms.

Ask your doctor if you have any questions why Oralair has been prescribed for you.

Oralair is not addictive.

This medicine is available only with a doctor's prescription.

Before you are given Oralair

Do not take Oralair if:

- You are hypersensitive (allergic) to any of the other ingredients of Oralair;
- You suffer from severe and/or unstable asthma or experienced severe asthma exacerbation within the last 3 months;
- Your forced expiratory volume in one second (FEV1) is below 70% as assessed by your doctor;
- You have an illness which affects the immune system, you are taking medicines which suppress the immune system or if you have cancer;
- You have mouth ulcers or mouth infections. Your doctor may recommend delaying the start of the treatment or stopping treatment until your mouth has healed.

Do not start taking ORALAIR if you are pregnant.

If you are not sure if you should be taking Oralair, talk to your doctor.

Before you start your treatment with Oralair:

Take special care with Oralair:

Talk to your doctor before taking ORALAIR if:

- You experience severe allergic symptoms, such as difficulty in swallowing or breathing, changes in your voice, hypotension (low blood pressure) or a feeling of a lump in the throat. Stop the treatment and contact your doctor immediately or go to the Emergency Department at your nearest hospital
- You have previously had a severe allergic reaction to a drug with allergen extracts.
- Your asthma symptoms get noticeably worse than normal. Stop treatment and contact your doctor immediately.
- You have a cardiovascular disease.
- You are taking a beta blocker (i.e., a class of drugs often prescribed for heart conditions and high blood pressure but also present in some eye drops and ointments), as this drug may decrease the effectiveness of adrenaline, a medicine used to treat serious allergic reactions.
- You are taking MAOIs, tricyclic antidepressants and COMT inhibitors. Allergen immunotherapy in patients treated with mono amine oxidase inhibitors (MAOIs) or tricyclic antidepressants or for Parkinson's disease with COMT inhibitors should be considered carefully as these treatments could potentiate the effect of adrenaline (epinephrine). You need mouth surgery or a tooth extraction, you should temporarily stop treatment with ORALAIR until completely healed.
- You have an autoimmune disease in remission
- You have any history of allergic inflammation of the oesophagus (eosinophilic oesophagitis). During treatment with Oralair, if you have severe or persistent upper abdominal pain, swallowing difficulties or chest pain, please contact your doctor who may reconsider your treatment.

Talk to your doctor about:

- Any recent disease you may have had,
- Personal or family history of any disease which could affect your immune system,
- If your allergic illness has recently worsened.

If you take asthma controller and/or reliever medications, do not interrupt your asthma treatment without your doctor's advice as this may worsen the asthma symptoms.

You can expect some mild to moderate localised allergic reactions during your treatment. If those reactions are severe, talk to your doctor to see if you need any anti-allergic medicines such as antihistamines.

Taking other medicines

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking other allergy medicines such as antihistamines, asthma relief medication or steroids or a medication that blocks a substance called immunoglobulin E (IgE) e.g. omalizumab, discuss with your doctor whether to continue taking them. Do not stop taking these medicines before talking to your doctor. If you stop taking those allergy medicines you may experience more side effects during ORALAIR treatment.

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

At present there is no experience for the use of Oralair during pregnancy. Therefore, you should not start immunotherapy if you are pregnant. If you become pregnant, speak to your doctor about whether it is appropriate for you to continue treatment.

There is no experience for the use of Oralair during breast-feeding. No effects on infants who are breast-fed during treatment are anticipated. However, you should not start immunotherapy if you are breast-feeding. If you wish to breastfeed while on treatment, speak to your doctor about whether it is appropriate for you to continue treatment.

Driving and using machines

No effect on the capacity to drive or use machines has been observed with Oralair.

Important information about some of the ingredients of Oralair

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Your doctor will advise you.

Your doctor has more information on medicines to be careful with or avoid while taking Oralair.

How Oralair is given

Treatment should be started 4 months before the onset of the pollen season.

Always take Oralair exactly as your doctor has told you. Check with your doctor if you are not sure.

Oralair is prescribed by doctors with adequate training and experience in treatment of allergy. With prescriptions for children, the doctor will have the relevant experience in the treatment of children.

The first dose of Oralair should be taken under medical supervision. You should stay under medical observation for at least half an hour after taking the first dose. This is a precaution to monitor your sensitivity to the medicine. This gives you the opportunity to discuss possible side effects with your doctor.

Dosage

Adults, adolescents and children above the age of 5

The treatment is composed of a treatment initiation phase (first month of treatment, including a 3-day dose escalation) and a treatment continuation phase (maintenance dose).

Method of administration

Keep the tablet under your tongue until it completely dissolve (at least 2 minute) before you swallow it. On the second day, put two 100 IR tablets simultaneously under the tongue and then swallow after about 2 minute. It is advisable to take the tablet during the day, in an empty mouth. Do not eat or drink for at least 5 minutes.

Treatment initiation:

The treatment with ORALAIR should be initiated as follows:

Day 1	1 tablet of 100 IR
Day 2	2 tablets of 100 IR simultaneously
Day 3	1 tablet of 300 IR

Treatment continuation:

The maintenance dose for adults, adolescents and children over 5 years of age is 1 tablet of 300 IR per day. Treatment with the maintenance dose should be continued until the end of the pollen season. If necessary, your doctor may, at the same time, prescribe medication to treat the possible allergic symptoms.

There is no experience with Oralair in young children (younger than 5 years) and in patients over 65 years of age.

How long Oralair should be taken for?

Oralair is started 4 months before the pollen season and then continued until the pollen season ends. Each year your Doctor will assess if it is suitable for you to restart Oralair treatment. Results from a recent long term study have shown that patients treated over 3 consecutive pollen seasons with Oralair, did not require further treatment in the 4th year.

If you take more Oralair than you should

If you take more Oralair than you should, you may experience allergic symptoms including local symptoms from mouth and throat. If you experience severe symptoms, such as angioedema (i.e. swelling), difficulty in swallowing, difficulty in breathing, changes in voice, or a feeling of fullness in the throat, seek urgent medical advice.

Contact the Poisons Information Centre on (13 11 26 in Australia and 0800 POISON (0800 764 766) in New Zealand) for advice on the management of overdose.

If you forget to take Oralair

Do not take a double dose to make up for a forgotten dose.

If you interrupted treatment with Oralair for less than one week, you can take up treatment where you have left off.

If you stopped the treatment for more than 7 days, please ask your doctor how you should restart the treatment.

If you stop taking Oralair

If you stop taking Oralair before the full treatment end, you may not have an effect from the treatment.

If you have any further questions on the use of this product, ask your doctor.

Oralair helps most people with *allergies to the selected group of grass pollen* but they may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of these side effects.

Contact your doctor or nurse immediately if symptoms of an allergic reaction occur.

During treatment with Oralair, you will be exposed to substances that may cause application site reactions and/or symptoms, which affect the whole body. You may experience application site reactions (such as itching of the mouth and throat irritation). These reactions usually occur at the beginning of therapy and are temporary, generally diminishing over time.

Stop taking ORALAIR and contact your doctor or hospital immediately if you

experience any of the following symptoms:

- Rapid swelling of face, mouth, throat or skin
- Difficulties in swallowing
- Difficulties in breathing
- Voice changes
- Hypotension (low blood pressure)
- Feeling of fullness in the throat (like a swelling)
- Hives and itching of the skin

Treatment should only be resumed at the physician's instructions.

Other possible side effects include the following:

Very common (affects more than 1 in 10 people)

- Itchy mouth
- Throat irritation
- Headache

Common (affects less than 1 in 10 people):

- Inflammation in the eyes, itchy or watery eyes
- Itchy ears
- Rhinitis (stuffy nose, runny or itchy nose, sneezing, nasal discomfort), congestion of sinus
- Swelling or itching of lips or tongue, tongue pain
- Mouth disorders (such as dryness, tingling, numbness, inflammation, pain, blistering or swelling)
- Throat disorders (such as dryness, discomfort, pain, blistering or swelling), hoarseness, difficulty in swallowing
- Inflammation of the mouth, nose and throat inflammation
- Asthma, difficulty in breathing
- Cough
- Chest discomfort
- Heartburn, upset stomach, stomach pain, diarrhoea, vomiting, nausea
- Persistent skin condition characterized by dryness, redness and itching, hives, itching

Uncommon (affects less than 1 in 100 people):

- Swelling of the eyes, eye redness, dry eye
- Ear infection, dizziness, ear discomfort
- Mouth or tongue ulceration, swollen palate, inflammation of the gums or lips or tongue
- Salivary gland enlargement, overproduction of saliva
- Altered taste, belching
- Throat tightness, throat numbness, foreign body sensation in the throat
- Wheezing
- Allergic reaction with swelling of the face and throat, hypersensitivity
- Swollen lymph nodes
- Rash, acne, cold sores, skin lesions subsequent to scratching
- Depression, tiredness, sleepiness
- Flu-like illness

Rare (affects less than 1 in 1000 people):

- Swelling face, flushing
- Anxiety
- Increase of eosinophil count (related to immune system blood cells)

Side effects in children and adolescents

The following adverse reactions were more frequent in children and adolescents than in adults who received ORALAIR

Very common (affects more than 1 in 10 people)

- Cough
- Nose and throat inflammation
- Mouth oedema

Common (affects less than 1 in 10 people)

- Oral allergy syndrome
- Lip inflammation
- Lump feeling in the throat
- Tongue inflammation
- Ear discomfort

In children and adolescents, the following additional adverse reactions were also reported:

Common (affects less than 1 in 10 people)

- Bronchitis
- Tonsillitis

Uncommon (affects less than 1 in 100 people):

- Chest pain

Additional side effects experienced in actual use (post marketing experience, frequency unknown)

- Worsening of asthma
- Systemic allergic reaction
- Oesophageal inflammation

These do not represent all possible adverse drug reactions. For a full list of all reported adverse drug reactions refer to the Product Information or your Doctor.

After using Oralair

Storage

- Keep it where children cannot reach it
- Keep it in the original pack
- Keep it below 30°C.
- Do not use if past the expiry date which is stamped on the carton side panel

Product Description

Oralair Initiation Treatment sublingual tablets 100 IR and 300 IR contain a small blister with 3 tablets of 100 IR concentration and a large blister with 28 tablets of 300 IR concentration.

OR

Oralair Initiation Treatment sublingual tablets 100 IR and 300 IR contain a small blister with 3 tablets of 100 IR concentration and a large blister with 7 tablets of 300 IR concentration.

Oralair Continuation Treatment sublingual tablets 300 IR contain blisters with 30 tablets of 300 IR concentration. The continuation treatment is available in packs of 30, 90 or 100 tablets.

The tablets are round, biconvex, white to beige, and slightly speckled. The 100 IR tablet is engraved with 100 on both sides while the 300 IR tablet is engraved with 300 on both sides.

Presentation

The following pack sizes are available:

Oralair Initiation Treatment sublingual tablets 100 IR and 300 IR (AUST R 167565)

- Pack with 3 tablets 100 IR and 28 tablets 300 IR
- Pack with 3 tablets 100 IR and 7 tablets 300 IR

Oralair Continuation Treatment sublingual tablets 300 IR (AUST R 167566)

- Pack with 30 tablets
- Pack with 90 tablets
- Pack with 100 tablets

NAME AND ADDRESS OF THE SPONSOR IN AUSTRALIA:

Stallergenes Australia Pty Ltd
Suite 2408,
4 Daydream Street,
Warriewood,
New South Wales 2102
Ph: 1800 824 166

NAME AND ADDRESS OF THE SPONSOR IN NEW ZEALAND:

Stallergenes Greer New Zealand Limited
Level 1, 24 Manukau Road,
Epsom, Auckland 1023
Ph: 0800 824 166

Date Prepared April 2024